

We Claim:

- 1 1. An oral dosage form of modafinil comprising modafinil and one or more surface
2 active agents.
- 1 2. The oral dosage form of modafinil of claim 1, wherein:
2 the modafinil comprises fine and coarse modafinil particles;
3 at least 10% of the modafinil particles comprise coarse modafinil particles and have diameters
4 greater than 220 μm ; and
5 up to 90% of the modafinil particles comprise fine modafinil particles and have diameters less than
6 220 μm .
- 1 3. The oral dosage form of modafinil of claim 1, wherein:
2 the modafinil comprises fine and coarse modafinil particles;
3 at least 15% of the modafinil particles comprise coarse modafinil particles and have diameters
4 greater than 220 μm ; and
5 up to 85% of modafinil particles comprise fine modafinil particles and have diameters less
6 than 220 μm .
- 1 4. The oral dosage form of modafinil of claim 1, wherein:
2 the modafinil comprises fine and coarse modafinil particles;
3 at least 25% of the modafinil particles comprise coarse modafinil particles and have diameters
4 greater than 220 μm ; and
5 up to 75% of the modafinil particles comprise fine modafinil particles and have diameter less than
6 220 μm .
- 1 5. The oral dosage form of modafinil of claim 2, wherein the total specific surface area
2 of the fine modafinil particles is at least 0.2 m^2/g .
- 1 6. The oral dosage form of modafinil of claim 1, wherein the modafinil and the one or
2 more surface active agents are co-grinded and/or co-sifted.
- 1 7. The oral dosage form of modafinil of claim 1, wherein the surface active agent
2 comprises one or more of an anionic, cationic or non-ionic surface active agent.

1 8. The oral dosage form of modafinil of claim 7, wherein the anionic surface active
2 agent comprises one or more of sodium lauryl sulphate, sodium laurate, dialkyl sodium
3 sulfosuccinates, sodium stearate, potassium stearate, and sodium oleate.

1 9. The oral dosage form of modafinil of claim 8, wherein the anionic surface active
2 agent comprises sodium lauryl sulphate.

1 10. The oral dosage form of modafinil of claim 7, wherein the cationic surface active
2 agent comprise one or both of benzalkonium chloride and bis-2-hydroxyethyl oleyl amine.

1 11. The oral dosage form of modafinil of claim 7, wherein the non-ionic surface active
2 agent comprises one or more of polyoxyethylene sorbitan fatty acid esters, fatty alcohols, glyceryl
3 esters, fatty acid esters of fatty alcohols, and alcohols.

1 12. The oral dosage form of modafinil of claim 11, wherein the fatty alcohol comprises
2 one or more of lauryl, cetyl and stearyl alcohol.

1 13. The oral dosage form of modafinil of claim 11, wherein the glyceryl esters comprises
2 one or more naturally occurring monoglycerides, diglycerides and triglycerides.

1 14. The oral dosage form of modafinil of claim 11, wherein the alcohol is selected from
2 one or more of propylene glycol, polyethylene glycol, sorbitan, sucrose and cholesterol.

1 15. The oral dosage form of modafinil of claim 11, wherein the polyethylene sorbitan
2 fatty acid ester comprises polysorbate.

1 16. The oral dosage form of modafinil of claim 1, wherein the amount of surface active
2 agent comprises from about 0.2% to 10% by weight, of the total weight of the dosage form.

1 17. The oral dosage form of modafinil of claim 1, further comprising one or more
2 pharmaceutically inert carriers, wherein the one or more pharmaceutically inert carriers comprise
3 one or more of cellulose derivatives, silicate derivatives, and clays.

1 18. The oral dosage form of modafinil of claim 17, wherein the cellulose derivative
2 comprises one or both of microcrystalline cellulose and carboxymethylcellulose.

1 19. The oral dosage form of modafinil of claim 17, wherein the silicate derivative
2 comprises one or more of magnesium silicate, colloidal silicon dioxide, magnesium trisilicate, and
3 magnesium aluminum silicate.

1 20. The oral dosage form of modafinil of claim 17, wherein the clay comprises one or
2 more of veegum and bentonite.

1 21. The oral dosage form of modafinil of claim 1, wherein the amount of
2 pharmaceutically inert carrier comprises from about 2% to about 25% by weight, of total weight of
3 the dosage form.

1 22. The oral dosage form of modafinil of claim 1, wherein the dosage form comprises a
2 tablet, a capsule, or a pill.

1 23. The oral dosage form of modafinil of claim 22, wherein the dosage form comprises a
2 tablet.

1 24. The oral dosage form of modafinil of claim 1, wherein the dosage form further
2 comprises one or more pharmaceutically inert excipients.

1 25. The oral dosage form of modafinil of claim 24, wherein the pharmaceutically inert
2 excipient comprises one or more of diluents, binders, disintegrants, lubricants/glidants and colors.

1 26. A process for preparing an oral dosage form of modafinil, the process comprising the
2 steps of:

- 3 a. mixing modafinil and one or both of one or more surface active agents and one or more
4 pharmaceutically inert carriers;
- 5 b. grinding and/or sifting the mix of step a;
- 6 c. combining with pharmaceutically inert excipients; and
- 7 d. compressing or filling into a suitable dosage form.

1 27. The process according to claim 26, wherein:
2 the modafinil comprises fine and coarse modafinil particles;
3 at least 10% of the modafinil particles comprise coarse modafinil particles and have bn diameters
4 greater than 220 μm ; and
5 up to 90% of the modafinil particles comprise fine modafinil particles and have diameters less than
6 220 μm .

1 28. The process according to claim 26, wherein:
2 the modafinil comprises fine and coarse modafinil particles;
3 at least 15% of the modafinil particles comprise coarse modafinil particles and have diameters
4 greater than 220 μm ; and
5 up to 85% of the modafinil particles comprise fine modafinil particles and have diameters less than
6 220 μm .

1 29. The process according to claim 27, wherein:
2 the modafinil comprises fine and coarse modafinil particles;
3 at least 25% of the modafinil particles comprise coarse modafinil particles and have diameters
4 greater than 220 μm ; and
5 up to 75% of the modafinil particles comprise fine modafinil particles and have diameters less than
6 220 μm .

1 30. The process according to claim 26, wherein the total specific surface area of the fine
2 modafinil particles is at least 0.2 m^2/g .

1 31. The process according to claim 26, wherein the dosage form comprises one or more
2 of a tablet, a capsule, and a pill.

1 32. The process according to claim 31, wherein the dosage form comprises a tablet.

1 33. The process according to claim 32, wherein the tablet is prepared by one or more of a
2 process of wet granulation, dry granulation, or direct compression method.

1 34. The process according to claim 33, wherein the tablet is prepared by a wet
2 granulation method.

1 35. The process according to claim 33, wherein the tablet is prepared by a dry
2 granulation method.

1 36. The process according to claim 33, wherein the tablet is prepared by a direct
2 compression method.

1 37. The process according to claim 31, wherein the dosage form comprises a capsule.

1 38. The process according to claim 32, wherein the dosage form is coated with one or
2 more functional and/or non-functional layers.

1 39. A method of treating one or both of narcolepsy and idiopathic hypersomnia by
2 administering an oral dosage form of modafinil, the dosage form comprising coarse and fine
3 modafinil particles and one or more surface active agents, wherein the fine modafinil particles have
4 diameters less than 220 μm .

1 40. The method according to claim 39, wherein at least 10% of the modafinil particles
2 have diameters greater than 220 μm .

1 41. The method according to claim 40, wherein at least 15% of the modafinil particles
2 have diameters greater than 220 μm .

1 42. The method according to claim 41, wherein at least 25% of the modafinil particles
2 have diameters greater than 220 μm .

1 43. The method according to claim 39, wherein the total specific surface area of the fine
2 modafinil particles is at least 0.2 m^2/g .

1 44. A mixture comprising modafinil particles and one or both of one or more surface
2 active agents and one or more pharmaceutically inert carriers, wherein the mixture is one or both of
3 co-grinded and co-sifted.

1 45. The mixture according to claim 44, wherein:
2 at least 10% of the modafinil particles are coarse and have diameters greater than 220 μm ;
3 and
4 up to 90% of the modafinil particles are fine and have diameters less than 220 μm .

1 46. The mixture according to claim 45, wherein:
2 at least 15% of the modafinil particles are coarse and have diameter greater than 220 μm ;
3 and
4 up to 85% of the modafinil particles are fine having diameter less than 220 μm .

1 47. The mixture according to claim 46, wherein:

2 at least 25% of the modafinil particles are coarse and have diameters greater than 220 μm ;
3 and
4 up to 75% of the modafinil particles are fine and have diameters less than 220 μm .

1 48. The mixture according to claim 44, wherein the total specific surface area of the fine
2 modafinil particles is at least $0.2 \text{ m}^2/\text{g}$, the fine modafinil particles having diameters less than 220
3 μm .

1 49. An oral dosage form of modafinil comprising modafinil and one or more surface
2 active agents, wherein the one or more surface active agents comprises one or more of an anionic,
3 cationic or non-ionic surface active agent.

1 50. The oral dosage form of modafinil of claim 49, wherein:
2 the modafinil comprises fine and coarse modafinil particles;
3 at least 10% of the modafinil particles comprise coarse modafinil particles and have diameters
4 greater than 220 μm ; and
5 up to 90% of the modafinil particles comprise coarse modafinil particles and have diameters less
6 than 220 μm .

1 51. The oral dosage form of modafinil of claim 49, wherein:
2 the anionic surface active agent comprises one or more of sodium lauryl sulphate, sodium laurate,
3 dialkyl sodium sulfosuccinates, sodium stearate, potassium stearate, and sodium oleate;
4 the cationic surface active agent comprises one or both of benzalkonium chloride and bis-2-
5 hydroxyethyl oleyl amine; and
6 the non-ionic surface active agent comprises one or more of polyoxyethylene sorbitan fatty acid
7 esters, fatty alcohols, glyceryl esters, fatty acid esters of fatty alcohols, and alcohols.

1 52. The oral dosage form of modafinil of claim 50, further comprising one or more
2 pharmaceutically inert carriers, wherein the one or more pharmaceutically inert carriers comprise
3 one or more of cellulose derivatives, silicate derivatives, and clays.

1 53. The oral dosage form of modafinil of claim 49, further comprising one or more
2 additional active pharmaceutical ingredients.

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- 1 54. An oral dosage form of modafinil comprising modafinil and one or both of one or
2 more surface active agents and one or more pharmaceutically inert carriers;
3 wherein the one or more surface active agents comprise one or more of an anionic, cationic or non-
4 ionic surface active agent; and
5 wherein the one or more pharmaceutically inert carrier comprise clay.